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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,826	06/01/2004	Tishu Cai	38-21(52501)B	3825

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MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167

EXAMINER

ZHENG, LI

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/709,826	Applicant(s) CAI ET AL.	
	Examiner Li Zheng	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4112005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-28, in the reply filed on 10/13/2006 is acknowledged. The traverse is on the ground that there is no undue burden to search for all claims. The examiner maintains that the search and examining of all groups is undue, as each group requires searching for different construct components and analysis of unrelated literatures.

The requirement is deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 1-28 are objected to because of the following informalities: brackets together with a claim number in between, preceding each of the claims, need to be removed. In addition, the claims have such a large type font that it is difficult to read. All future copies of the claims must be provided using the guidelines for fonts provided on the MPEP 37 CFR 1.52, which suggest a font size of 12 in Arial, Times Roman or Courier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Agrobacterium*-mediated transformation for maize using immature embryo and the bacterium inoculation process performed by submersing the embryos in *Agrobacterium* solution, does not reasonably provide enablement for all transformation methods, all cereal plants, all explants, or other. The specification does not enable any person skilled in the art to which it pertains, or other bacterium inoculation processes contemplated in the specification with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches a modified maize transformation method in which the overall selection time is shortened (paragraph [085]); the selection stringency is optimized (paragraph [085]); and selection temperature is elevated for increased transformation efficiency (paragraphs [0099]-[0100] and Table 3). The specification also contemplates that exposure to anerobiosis conditions during the *Agrobacterium* inoculation can be limited by limiting the time of submersion in the *Agrobacterium* solution, inoculating with a small drop of *Agrobacterium* solution, or inoculating with filter paper saturated with the *Agrobacterium* solution (paragraph [0012]).

However, the claimed method is only tested and optimized using maize immature embryos in *Agrobacterium*-mediated transformation. There is no evidence in the specification or the prior art that such method and its optimization would work for other cereal plants, other transformation methods, or other explants. In fact, the specification

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admits that numerous modifications in selective regimes, media, and growth conditions that can be varied depending on the plant system and the selective agent (the paragraph bridging pages 22-23).

Plant transformation procedures employing plant tissue culture protocols are unpredictable. "Plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one" (Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230). Therefore it is unpredictable that transformation protocols and methods that work for maize would function as desired for cereal other than maize.

Further, Applicant claims all methods of plant transformation, including particle bombardment, electroporation, microinjection, macroinjection, vacuum infiltration, sonication, Agrobacterium transformation, and all combinations and permutations of these methods. Applicant teaches Agrobacterium transformation. Agrobacterium transformation is not representative of all transformation methods. Agrobacterium is "special" in that it is a biological method, which uses plant microbial interactions to transfer DNA from the Agrobacterium genome to the genome of the plant.

Furthermore, Tisserat teaches that the regeneration of plants from explants is unpredictable, and explant selection is critical for successful plant regeneration. See Tisserat, in Plant Cell Culture, ed R.A. Dixon, 1985, IRL Press, Oxford, pages 79-90, especially page 80, Table 1, page 82, and Table 4, pages 85-90. There is no evidence that cereal tissues except for immature embryos and embryogenic calli can be

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successfully used in *Agrobacterium*-mediated transformation (Hansen et al., page 229, the first paragraph of the left column).

Finally, The specification also contemplates that exposure to anerobiosis conditions during the *Agrobacterium* inoculation can be limited by limiting the time of submersion in the *Agrobacterium* solution, inoculating with a small drop of *Agrobacterium* solution, or inoculating with filter paper saturated with the *Agrobacterium* solution (paragraph [0012]). Without working example, applicants claim inoculating with 1 ul of *Agrobacterium* solution, or inoculating with filter paper saturated with the *Agrobacterium* solution as bacteria inoculation processes. However, Hansen et al. teach that monocots are generally not natural host for *Agrobacterium* and the success of *Agrobacterium*-mediated transformation using immature embryos and embryogenic calli of monocot is attributed to the addition of surfactant to the inoculation medium (Hansen et al., page 229, the first paragraph of the left column). It is unpredictable that the claimed modified inoculation processes would still allow the *Agrobacteria* infect maize immature embryos efficiently or not.

Applicants have provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which are excessive experimentation and an undue burden.

See *Genentech Inc. v. Novo Nordisk, A/S* (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

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Given breadth of the claims, lack of further guidance and working example, and unpredictability of the cereal transformation art, undue experimentation would be required for a person skilled in the art to practice the invention in full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6-10, 14-16, 20-24 and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frame et al. (2002, Plant Physiology 129:13-22) in evidence of Zhao et al. (2001, Molecular Breeding 8:323-333).

Frame et al. teach a reproducible method for maize transformation using an Agrobacterium standard binary vector system (page 14, second paragraph of the right column). Particularly the embryos infection was accomplished by gently inverting the tube 20 times before resting it upright for 5 min with embryos submerged (page 20, the second paragraph of the right column). After 4 to 7 days on resting medium (28 °C,

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dark), embryos were transferred to selection medium containing bialaphos. Selection was increased 2 weeks later. Putative transformed events were identified as early as 5 weeks after infection (page 21, the second paragraph of the left column).

The claims require temperature for selection step being between about 28 °C to about 35 °C. Frame et al. teach selection step as claimed in the instant application but does not mention the selection temperature as claimed. The examiner is unable to determine whether the prior art disclosure possesses the unrecited characteristics or property. However, Frame et al. states that the method is modified from Zhao et al. and Zhao et al. teach that The embryos were moved to selection medium and kept in the dark at 28 °C until herbicide resistant callus proliferated (page 324, the 1st paragraph of the right column).

Further, claims 6 and 20 require limitation of selection being performed in a single vessel without replacing or replenishing the selection media during the selection. Frame et al. mention that the herbicide concentration in selection media was increased after two weeks but do not mention whether the selection media was replaced or not (the concentration of the selection could be adjusted by just adding herbicide solution without replacing the old selection media).

See *In re Best* 195 USPQ 430, 433 (CCPA 1977). The examiner is not in a position to make a conclusion of "inherency/anticipation" or "obviousness" since the record does not allow one to determine if and how the claimed subject matter differ from the prior art. Accordingly, the burden shifts to the Applicant to provide evidence that the prior art neither anticipates nor renders obvious the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10, 14-24, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frame et al. (2002, Plant Physiology 129:13-22) in view of Zhao et al. (2001, Molecular Breeding 8:323-333).

Claims 1, 6-10, 14-16, 20-24 and 28 are rejected for the reason as discussed above. Claims 2-5 and 17-19 contain further limitations which are the period of time for selection being between about 7 days and about 28 days or being about 1-14 days, as well as the selection temperature being about 30 °C to about 34 °C or being 30 °C. However, those added limitations are considered optimization of process parameters which would not confer patentable distinction to the claimed invention. In fact, the specification mentions optimization by modifying variables on pages 18 (1st paragraph) and 22-24 (the paragraph bridging pages 22-23, for example).

Conclusion

Claims 1-28 are rejected.

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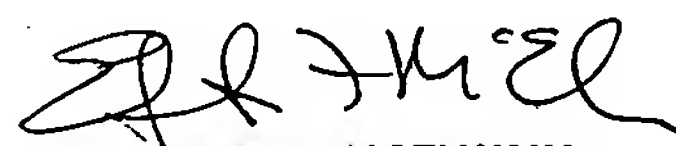
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031.

The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ELIZABETH MCELWAIN
PRIMARY EXAMINER